UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

MEDTECH PRODUCTS, INC.,

Plaintiff,

v.

RANIR, LLC, et al.,

Defendants.

MEDTECH PRODUCTS, INC.,

Plaintiff,

v.

DENTEK ORAL CARE, INC.,

Defendant.

MEDTECH PRODUCTS, INC.,

Plaintiff,

v.

POWER PRODUCTS, INC.,

Defendant.

07 CV 03302-UA-LMS

ANSWER AND COUNTERCLAIM OF DENTEK ORAL CARE, INC.

DEMAND FOR JURY TRIAL

ECF Filed

Defendant DenTek Oral Care, Inc. (hereinafter "DenTek"), by and through its undersigned attorney, submits the following Answer to the Complaint for Injunctive Relief and Money Damages ("the Complaint") of Plaintiff Medtech Products, Inc. (hereinafter "Medtech"):

- 1. DenTek admits that Medtech has instituted an action for infringement of a patent and a copyright, unfair competition, violation of the Lanham Act, violation of common law trademark rights, and violation of a New York consumer protection act but denies that Medtech has grounds exist for such an action.
- 2. DenTek admits that this case involves a dental protector but denies that the dental protector in question is designed to protect the teeth and jaw from bruxism, denies that NIGHTGUARDTM has any trademark significance, and is without information sufficient to

form a belief as to the truth or falsity of the remaining allegations of paragraph 2 of the Complaint and therefore, denies them.

- 3. DenTek admits that Medtech has been selling a dental protector, denies that NIGHTGUARDTM has brand significance and is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 3 of the Complaint and therefore, denies them.
- 4. DenTek is without information sufficient to form a belief as to the truth or falsity of the allegations that Medtech's dental protector is covered by patents and therefore denies them. DenTek denies all the remaining allegations of paragraph 4 of the Complaint.
- 5. DenTek admits that it markets and sells in the OTC market a dental protector in interstate commerce for bruxism, but denies all other allegations of paragraph 5 of the Complaint.
 - 6. DenTek denies all the allegations of paragraph 6 of the Complaint.
- 7. DenTek denies the allegations of the first sentence of paragraph 7 of the Complaint. DenTek is without information sufficient to form a belief as to the truth or falsity of the allegations of the second sentence of paragraph 7 of the Complaint and therefore, denies them.
 - 8. DenTek denies all the allegations of paragraph 8 of the Complaint.
 - 9. DenTek denies all the allegations of paragraph 9 of the Complaint.

PARTIES, JURISDICTION & VENUE

- 10. DenTek is informed and believes, and therefore admits, that Medtech is a corporation organized and existing under the laws of Delaware having a principal place of business at 90 North Broadway, Irvington, New York 10533.
 - 11. DenTek admits the allegations of paragraph 11 of the Complaint.

- 12. DenTek admits that the Complaint sets forth allegations under 15 USC §§ 1116-18 or 1125(a), 17 USC §§ 101 *et seq.*, 35 USC § 271, or the laws of the State of New York, but denies that the Medtech has a meritorious claim under them.
- 13. DenTek admits that this Court has jurisdiction over the subject matter of this action pursuant to 28 USC §§ 1331, 1338 (a) and (b), and 15 USC § 1121, and that there is diversity of citizenship between the parties. DenTek is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 13 of the Complaint and therefore, denies them.
 - 14. DenTek admits the allegations of paragraph 14 of the Complaint.
- 15. DenTek admits that venue is proper in this District pursuant to 28 USC §§ 1391(b) and (c) and denies all the remaining allegations of paragraph 15 of the Complaint.

FACTS COMMON TO ALL COUNTS

- 16. DenTek admits that Medtech has been selling a dental protector in the United States but denies that the dental protector in question is designed to protect the teeth and jaw from bruxism, denies that NIGHTGUARD™ has trademark significance and is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 16 of the Complaint and therefore, denies them.
- 17. DenTek denies that NIGHTGUARDTM is a mark and is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of the first sentence of paragraph 17 of the Complaint and therefore denies them. DenTek denies all the allegations of the second sentence of paragraph 17 of the Complaint.
 - 18. DenTek denies all the allegations of paragraph 18 of the Complaint.
 - 19. DenTek denies all the allegations of paragraph 19 of the Complaint.

- 20. DenTek admits that what appears to be an incomplete copy of FDA documentation providing approval of a Medtech dental protector is attached as Exhibit A, admits that Medtech dental protectors were sold OTC without FDA approval over an extended period of time, denies that Medtech originated the market for OTC dental protective devices for bruxism and is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 20 of the Complaint and therefore denies them.
 - 21. DenTek denies all the allegations of paragraph 21 of the Complaint.
- 22. DenTek admits that Exhibit B of the Complaint appears to be a copy of packaging of a Medtech dental protector, that it lists on its side panel certain warnings and instructions, and that it contains wording as shown. DenTek admits that the packaging of the Medtech dental protector includes the phrase recited in paragraph 22 of the Complaint in red and purple letters but denies the remaining allegations of the third sentence of paragraph 22. DenTek denies the allegations of the fourth sentence of paragraph 22 of the Complaint and is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 22 of the Complaint and therefore denies them.
- 23. DenTek admits that Exhibit C appears to be an insert from a Medtech dental protector describing aspects of the product and its use. DenTek is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 23 of the Complaint and therefore denies them.
 - 24. DenTek denies all the allegations of paragraph 24 of the Complaint.
 - 25. DenTek denies all the allegations of paragraph 25 of the Complaint.
 - 26. DenTek denies all the allegations of paragraph 26 of the Complaint.

- 27. DenTek denies that NIGHTGUARDTM has brand significance and is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 27 of the Complaint and therefore, denies them.
- 28. DenTek denies that the Medtech dental protector remains the recognized category leader of OTC dental protectors. DenTek is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 28 of the Complaint therefore, denies them.
- 29. DenTek denies the allegations of the first sentence of paragraph 29 of the Complaint. DenTek admits that an application for NIGHTGUARD was filed as a trademark (Ser. No. 77/056,556) in which the United States Patent & Trademark Office has issued a rejection of Medtech's application, *inter alia*, on the grounds that the proposed mark is "merely descriptive" and "the proposed mark appears to be generic as applied to the goods and, therefore, incapable of functioning as a source-identifier for applicant's goods." DenTek denies the remaining allegations of the second sentence of paragraph 29.
- 30. DenTek admits that US Patent No. 6,830,051 ("the '051 patent") was issued by the USPTO on December 14, 2004 and that Exhibit D appears to be a copy of that patent. DenTek denies that the patent is valid and enforceable and is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 30 of the Complaint and therefore denies them.
- 31. DenTek admits that the USPTO has issued US patents D504,744, D382,965, and 5,566,684. DenTek is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 31 of the Complaint and therefore denies them.

- 32. DenTek is without information sufficient to form a belief as to the truth or falsity of the statement that Medtech dental protectors have long been and are currently marked with the applicable US Patent numbers and therefore, denies it. Paragraph 32 of the Complaint contains arguments and conclusions of law to which no admission or denial is required.

 DenTek denies all the remaining allegations of paragraph 32 of the Complaint.
- 33. DenTek admits that Exhibit E of the Complaint appears to be a copy of Copyright Registration of U.S. Reg. No. TX 6-536-309 ("the '309 registration"), and is without information sufficient to form a belief as to the truth or falsity of the remaining allegations of the first two sentences of paragraph 33 and therefore denies them. DenTek denies the allegations of the third sentence of paragraph 33 of the Complaint.
- 34. DenTek is without information sufficient to form a belief as to the truth or falsity of the allegations that the packaging and fitting instructions of the Medtech dental protectors carry a copyright notice and therefore denies them. Paragraph 34 of the Complaint contains arguments and conclusions of law to which no admission or denial is required.

 DenTek denies all the remaining allegations of paragraph 34 of the Complaint.
- 35. DenTek admits that it markets, distributes and sells a dental protector in the United States and denies the remaining allegations of paragraph 35 of the Complaint.
 - 36. DenTek denies all the allegations of paragraph 36 of the Complaint.
- 37. DenTek admits that Exhibit F appears to be a true and correct copy of the packaging of a DenTek product and that this packaging contains the phrasing shown on the packaging. DenTek denies all remaining allegations of paragraph 37 of the Complaint.
- 38. DenTek is without information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 38 of the Complaint and therefore, denies them.

- 39. DenTek denies all the allegations of paragraph 39 of the Complaint.
- 40. DenTek admits that it has received a Section 510(k) pre-market authorization from the FDA for marketing the DenTek dental protector, identified MedTech's product as a predicate device and made the assertions that appear in its 510k filings. DenTek denies all the other allegations of paragraph 40 of the Complaint.
 - 41. DenTek denies all the allegations of paragraph 41 of the Complaint.
- 42. DenTek admits that Exhibit G appears to be a copy of fitting instructions for DenTek's dental protector product and denies the remaining allegation of paragraph 42 of the Complaint.
- 43. In response to the first sentence of paragraph 43 of the Complaint, DenTek admits that Exhibit C appears to be a copy of the fitting instructions for Medtech's dental protector and Exhibit G appears to be a copy of the fitting instructions for DenTek's product, but DenTek denies the statements made in the chart following paragraph 43 of the Complaint to the extent that the text in the chart deviates from the wording of Exhibit C or Exhibit G. DenTek denies that it has copied any protectable components of the Medtech fitting instructions or that DenTek's at home fitting instructions have "closely copied" the Medtech fitting instructions. DenTek also denies that "substantial portions" of the Medtech fitting instructions or a "pertinent part" of Medtech's phrasing are copied on the packaging of the DenTek dental protector. DenTek denies all the remaining allegations of paragraph 43 of the Complaint.
 - 44. DenTek denies all the allegations of paragraph 44 of the Complaint.
 - 45. DenTek denies all the allegations of paragraph 45 of the Complaint.

- 46. DenTek is without information sufficient to form a belief as to the truth or falsity of the statements that considerable time, effort and money were spent in obtaining shelf space in retail outlets by Medtech and therefore, denies them. DenTek denies all the remaining allegations of paragraph 46 of the Complaint.
 - 47. DenTek denies all the allegations of paragraph 47 of the Complaint.
- 48. DenTek is without information sufficient to form a belief as to the truth or falsity of the allegations regarding the terms "SLEEP RIGHT SELECTTM", "VERSACRYLTM", and "REST ASSUREDTM" and therefore, denies them. DenTek denies the remaining allegations of paragraph 48 of the Complaint.
- 49. DenTek admits that MedTech seeks the relief requested in its Complaint, denies that MedTech is entitled to any relief and denies the remaining allegations of paragraph 49 of the Complaint.

COUNT I

(Infringement of U.S. Patent No. 6,830,051)

- 50. DenTek incorporates its responses to each and every allegation of paragraphs 1 through 49 of the Complaint as if expressly stated herein.
- 51. DenTek is without information sufficient to form a belief as to the truth of the allegations of the first sentence of paragraph 51 of the Complaint and therefore denies them. DenTek admits that it sells and offers to sell a dental protector product and denies the remaining allegations of paragraph 51 of the Complaint.
 - 52. DenTek denies all the allegations of paragraph 52 of the Complaint.
 - 53. DenTek denies all the allegations of paragraph 53 of the Complaint.
 - 54. DenTek denies all the allegations of paragraph 54 of the Complaint.
 - 55. DenTek denies all the allegations of paragraph 55 of the Complaint.

COUNT II

Document 15

(Lanham Act- Unfair Competition/Use of False Designation in Interstate Commerce)

- 56. DenTek incorporates its responses to each and every allegation of paragraphs 1 through 55 of the Complaint as if expressly stated herein.
- 57. DenTek admits that it sells and offers to sell a nightguard for dental protection and that the term is used as a generic description of the product. DenTek denies the remaining allegations of paragraph 57 of the Complaint.
 - 58. DenTek denies all the allegations of paragraph 58 of the Complaint.
 - 59. DenTek denies all the allegations of paragraph 59 of the Complaint.
 - 60. DenTek denies all the allegations of paragraph 60 of the Complaint.
 - 61. DenTek denies all the allegations of paragraph 61 of the Complaint.
 - 62. DenTek denies all the allegations of paragraph 62 of the Complaint.
 - 63. DenTek denies all the allegations of paragraph 63 of the Complaint.

COUNT III

(Infringement of U.S. Copyright TX 6-536-309)

- 64. DenTek incorporates its responses to each and every allegation of paragraphs 1 through 63 of the Complaint as if expressly stated herein.
- 65. DenTek denies that it has copied any protectable components or any "substantial portions" of the Medtech material identified in the Copyright Registration.
 - 66. DenTek denies all the allegations of paragraph 66 of the Complaint.
 - 67. DenTek denies all the allegations of paragraph 67 of the Complaint.
 - 68. DenTek denies all the allegations of paragraph 68 of the Complaint.
 - 69. DenTek denies all the allegations of paragraph 69 of the Complaint.

COUNT IV

(Unfair Competition)

- 70. DenTek incorporates its responses to each and every allegation of paragraphs 1 through 69 of the Complaint as if expressly stated herein.
 - 71. DenTek denies all the allegations of paragraph 71 of the Complaint.
 - 72. DenTek denies all the allegations of paragraph 72 of the Complaint.
 - 73. DenTek denies all the allegations of paragraph 73 of the Complaint.
 - 74. DenTek denies all the allegations of paragraph 74 of the Complaint.
 - 75. DenTek denies all the allegations of paragraph 75 of the Complaint.

COUNT V

(Unjust Enrichment)

- 76. DenTek incorporates its responses to each and every allegation of paragraphs 1 through 75 of the Complaint as if expressly stated herein.
 - 77. DenTek denies all the allegations of paragraph 77 of the Complaint.
 - 78. DenTek denies all the allegations of paragraph 78 of the Complaint.
 - 79. DenTek denies all the allegations of paragraph 79 of the Complaint.

COUNT VI

(Violation of New York Consumer Protection Law)

- 80. DenTek incorporates its responses to each and every allegation of paragraphs 1 through 79 of the Complaint as if expressly stated herein.
 - 81. DenTek denies all the allegations of paragraph 81 of the Complaint.
 - 82. DenTek denies all the allegations of paragraph 82 of the Complaint.
 - 83. DenTek denies all the allegations of paragraph 83 of the Complaint.
 - 84. DenTek denies all the allegations of paragraph 84 of the Complaint.

- 85. DenTek denies all the allegations of paragraph 85 of the Complaint.
- 86. DenTek denies all the allegations of paragraph 86 of the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

87. The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

88. DenTek has not directly infringed, has not contributorily infringed, and has not induced infringement of any claim of the '051 patent under 35 U.S.C. § 271, and is not liable for any acts of infringement of the '051 patent.

THIRD AFFIRMATIVE DEFENSE

89. Upon information and belief, the claims of the '051 patent are invalid, void and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, and 287.

FOURTH AFFIRMATIVE DEFENSE

90. The term nightguard is commonly used in the industry to describe a dental protector used at night, is commonly descriptive, and is not capable of possessing, or developing through use, any trademark significance.

FIFTH AFFIRMATIVE DEFENSE

NIGHTGUARD is generic. 91.

SIXTH AFFIRMATIVE DEFENSE

92. Plaintiff's alleged NIGHTGUARD mark does not function as a trademark.

SEVENTH AFFIRMATIVE DEFENSE

93. U.S. Reg. No. TX 6-536-309 registration is invalid.

EIGHTH AFFIRMATIVE DEFENSE

94. The Medtech At-Home Fitting Instructions insert does not contain copyrightable subject matter.

NINTH AFFIRMATIVE DEFENSE

95. DenTek has not copied any copyrightable subject matter of the Medtech At-Home Fitting Instructions insert.

TENTH AFFIRMATIVE DEFENSE

96. Plaintiff is not entitled to statutory damages or attorneys' fees under 17 U.S.C. Section 504 and 505.

ELEVENTH AFFIRMATIVE DEFENSE

97. Plaintiff's claims are barred by Plaintiff's unclean hands.

TWELFTH AFFIRMATIVE DEFENSE

98. Plaintiff is estopped to maintain each cause of action.

THIRTEENTH AFFIRMATIVE DEFENSE

99. Plaintiff has failed to mitigate damages.

MEDTECH'S PRAYER FOR RELIEF

- DenTek denies that Medtech is entitled to the relief requested in paragraph 1 of the Prayer for Relief in the Complaint.
- 2. DenTek denies that Medtech is entitled to the relief requested in paragraph 2 of the Prayer for Relief in the Complaint.

- 3. DenTek denies that Medtech is entitled to the relief requested in paragraph 3 of the Prayer for Relief in the Complaint.
- 4. DenTek denies that Medtech is entitled to the relief requested in paragraph 4 of the Prayer for Relief in the Complaint.
- 5. DenTek denies that Medtech is entitled to the relief requested in paragraph 5 of the Prayer for Relief in the Complaint.
- 6. DenTek denies that Medtech is entitled to the relief requested in paragraph 6 of the Prayer for Relief in the Complaint.
- 7. DenTek denies that Medtech is entitled to the relief requested in paragraph 7 of the Prayer for Relief in the Complaint.
- 8. DenTek denies that Medtech is entitled to the relief requested in paragraph 8 of the Prayer for Relief in the Complaint.
- 9. DenTek denies that Medtech is entitled to the relief requested in paragraph 9 of the Prayer for Relief in the Complaint.
- 10. DenTek denies that Medtech is entitled to the relief requested in paragraph 10 of the Prayer for Relief in the Complaint.
- 11. DenTek denies that Medtech is entitled to the relief requested in paragraph 11 of the Prayer for Relief in the Complaint.
- 12. DenTek denies that Medtech is entitled to the relief requested in paragraph 12 of the Prayer for Relief in the Complaint.

COUNTERCLAIM

PARTIES

- 1. Defendant-Counterclaim Plaintiff DenTek is a corporation organized and existing under the laws of Tennessee, with a principal place of business at 307 Excellence Way, Maryville, Tennessee 37801.
- 2. Upon information and belief, Plaintiff-Counterclaim Defendant Medtech is a corporation organized and existing under the laws of Delaware having a principal place of business at 90 North Broadway, Irvington, New York 10533.

JURISDICTION AND VENUE

- 3. This Court has jurisdiction under 28 U.S.C. §§ 1331, 1338, 1367, 2201 and 2202.
 - 4. Venue in this District is proper under 28 U.S.C. §§ 1391 and 1400.

COUNT I

(Non-infringement of U.S. Patent No. 6,830,051)

- 5. DenTek repeats and realleges all of its allegations in paragraphs 1 through 4 of the Counterclaim as if expressly stated herein.
- 6. Medtech claims to be the owner of the '051 patent and has claimed that DenTek has infringed that patent.
- 7. There is an actual, substantial, and continuing justiciable controversy between DenTek and Medtech regarding the infringement, validity and enforceability of the '051 patent.
- 8. DenTek has not infringed any valid and enforceable claim of the '051 patent.

9. DenTek is entitled to a declaration that it does not infringe any valid and enforceable claim of the '051 patent.

COUNT II

(Invalidity and/or Unenforceability of U.S. Patent No. 6,830,051)

- 10. DenTek repeats and realleges all of its allegations in paragraphs 1 through 4 of the Counterclaim as if expressly stated herein.
- 11. The claims of the '051 patent are invalid, void and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, and 287.
- 12. DenTek is entitled to a declaration that all claims of the '051 patent are invalid, void and/or unenforceable.

COUNT III

(Non-existence and Non-infringement of Medtech Trademark Rights)

- 13. DenTek repeats and realleges all of its allegations in paragraphs 1 through 4 of the Counterclaim as if expressly stated herein.
- 14. Medtech claims to be the owner of certain trademark rights in the term "NIGHTGUARD" and has applied to register same with the United States Patent & Trademark Office ("USPTO") through the filing of US Trademark Application Serial Number 77/056,556. The USPTO responded to Medtech's application with a rejection premised, inter alia, on the ground that the term is commonly descriptive of the device to which applied (a dental protector used at night) and provided examples of widespread use of nightguard in this common descriptive fashion.

- 15. Medtech possesses no rights in the term "nightguard" because this term is generic, commonly descriptive, incapable of acquiring trademark significance, and/or in the public domain.
- 16. DenTek is entitled to a declaration that Medtech does not possess any of the trademark rights to which it claims rights of ownership, that "nightguard" is generic, commonly descriptive, incapable of acquiring trademark significance, and/or in the public domain, and that DenTek has not infringed any Medtech trademark rights or trade dress rights asserted by Medtech in the Complaint.

COUNT IV

(Non-infringement of U.S. Copyright TX 6-536-309)

- 17. DenTek repeats and realleges all of its allegations in paragraphs 1 through 4 of the Counterclaim as if expressly stated herein.
- 18. Medtech claims to be the owner of U.S. Copyright TX 6-536-309 (the "309 registration") and claims that DenTek has infringed its rights.
- 19. There is an actual, substantial, and continuing justiciable controversy between DenTek and Medtech regarding the infringement and validity and enforceability of the TX 6-536-309 registration.
 - 20. DenTek has not infringed the TX 6-536-309 registration.
- 21. DenTek is entitled to a declaration that it does not infringe the TX 6-536-309 registration.

COUNT V

(Invalidity and/or Unenforceability of U.S. U.S. Copyright TX 6-536-309)

22. DenTek repeats and realleges all of its allegations in paragraphs 1 through 4 and 18 through 21 of the Counterclaim as if expressly stated herein.

- 23. The TX 6-536-309 registration is invalid because the work claimed therein is not original, lacks copyrightable subject matter, and/or contains works in the public domain.
- 24. DenTek is entitled to a declaration that the TX 6-536-309 registration is invalid, void and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, DenTek prays that the Court enter:

- A declaratory judgment that DenTek does not infringe any valid claim of the '051 A. patent under 35 U.S.C. § 271;
 - A declaratory judgment that the '051 patent is invalid and/or unenforceable; B.
- C. A declaratory judgment that the term "nightguard" is generic, commonly descriptive, incapable of acquiring trademark significance, and/or in the public domain, and that DenTek has not infringed any Medtech trademark rights or trade dress rights asserted by Medtech in the Complaint, and that acts performed by DenTek do not constitute unfair competition under the Lanham Act, 15 U.S.C. § 1125(a);
- D. A declaratory judgment that DenTek does not infringe the '309 registration under 17 U.S.C. § 501;
 - E. A declaratory judgment that the '309 registration is invalid and/or unenforceable;
- F. An Order enjoining and restraining Medtech Products Inc. and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from further charges of infringement or acts of enforcement based on the '051 patent or the '309 registration against DenTek, its actual and prospective customers, suppliers, clinical investigators, and anyone in privity with DenTek;

- G. An Order awarding DenTek costs and attorneys' fees related to this litigation; and
- H. An Order awarding DenTek such other further relief as the Court deems just and equitable.

JURY DEMAND

Defendant, DenTek Oral Care, Inc., demands a trial by jury as to all claims and issues so triable in the above-captioned case.

Dated: May 30, 2007 s/ Alan Federbush

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document was served on the following recipients by use of the Court's ECF system on May 30, 2007:

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Attorneys for Plaintiff

s/ Alan Federbush____ Alan Federbush